

gain access to the U.S. mainland because we are only 1,600 kilometers away from the U.S. mainland.

Since 1998 Mr. Speaker, close to 1000 Chinese nationals have entered the U.S. Virgin Islands to transit undetectably into the mainland. These landings have occurred mainly during the pre-dawn hours at one of the several cays on the Island of St. John. The sheer number of individuals who are able to infiltrate the island is indicia of vulnerability to a possible terrorist attack.

The lack of a Border Patrol Security Unit, has placed an unreasonable burden on other Federal agencies such as the Immigration and Customs Enforcement, ICE, which has to now spend considerable amount of man-hours apprehending, processing and detaining aliens in custody. This detracts from the time ICE would have to carryout its investigatory duties.

Just last month, there was an article published in the Economist Magazine describing the V.S. V.I as "America's most vulnerable point, a lovely place" but "woefully unprepared for a terrorist attack." The article points out that "illegal aliens land in the Virgin Islands openly and regularly, yet they are rarely caught." Having a Border Patrol unit in the Virgin Islands, Mr. Speaker, will not only greatly enhance the security of the Virgin Islands, but the entire Nation as well.

I urge my colleagues to support H. Res. 1030.

Mr. JONES of North Carolina. Mr. Speaker, I have no other speakers on H. Res. 1030, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Alabama (Mr. ROGERS) that the House suspend the rules and agree to the resolution, H. Res. 1030.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the resolution was agreed to.

A motion to reconsider was laid on the table.

MESSAGE FROM THE SENATE

A message from the Senate by Ms. Curtis, one of its clerks, announced that the Senate has passed without amendment a bill and a concurrent resolution of the House of the following titles:

H.R. 5187. An act to amend the John F. Kennedy Center Act to authorize additional appropriations for the John F. Kennedy Center for the Performing Arts for fiscal year 2007.

H. Con. Res. 480. Concurrent resolution to correct the enrollment of the bill H.R. 3127.

The message also announced that the Senate has passed with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 5574. An act to amend the Public Health Service Act to reauthorize support for graduate medical education programs in children's hospitals.

The message also announced that the Senate has passed a bill of the following title in which the concurrence of the House is requested:

S. 3421. An act to authorize major medical facility projects and major medical facility leases for the Department of Veterans Affairs for fiscal years 2006 and 2007, and for other purposes.

BIODEFENSE AND PANDEMIC VACCINE AND DRUG DEVELOPMENT ACT OF 2006

Mr. DEAL of Georgia. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5533) to prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes, as amended.

The Clerk read as follows:

H.R. 5533

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Biodefense and Pandemic Vaccine and Drug Development Act of 2006".

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Biomedical Advanced Research and Development Authority; National Biodefense Science Board.

Sec. 4. Clarification of countermeasures covered by Project BioShield.

Sec. 5. Technical assistance.

Sec. 6. Procurement.

SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY; NATIONAL BIODEFENSE SCIENCE BOARD.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by inserting after section 319K the following:

"SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

"(a) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

"(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

"(2) IN GENERAL.—The Secretary shall coordinate and oversee the acceleration of countermeasure and product advanced research and development by—

"(A) facilitating collaboration among the Department of Health and Human Services, other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

"(B) promoting countermeasure and product advanced research and development;

"(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act; and

"(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

"(3) DIRECTOR.—The BARDA shall be headed by a Director (referred to in this section as the 'Director') who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section.

"(4) DUTIES.—

"(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary shall—

"(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and rel-

evant persons with respect to countermeasure and product advanced research and development, including by—

"(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

"(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

"(ii) at least annually—

"(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

"(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

"(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section; and

"(iii) carry out the activities described in section 6 of the Biodefense and Pandemic Vaccine and Drug Development Act of 2006.

"(B) SUPPORT ADVANCED RESEARCH AND DEVELOPMENT.—To carry out the purpose described in paragraph (2)(B), the Secretary shall—

"(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

"(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

"(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development and innovation in such areas as the Secretary may identify as priority unmet need areas; and

"(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development.

"(C) FACILITATING ADVICE.—To carry out the purpose described in paragraph (2)(C) the Secretary shall—

"(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products; and

"(ii) ensure that, with respect to persons performing countermeasure and product advanced research and development funded under this section, such offices or employees provide such advice in a manner that is ongoing and that is otherwise designated to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure.

"(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

"(i) innovation in technologies that may assist countermeasure and product advanced research and development;

"(ii) research on and development of research tools and other devices and technologies; and

"(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.

"(5) TRANSACTION AUTHORITIES.—

"(A) OTHER TRANSACTIONS.—In carrying out the functions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have authority to enter into other transactions for countermeasure and product advanced research and development.

“(B) EXPEDITED AUTHORITIES.—

“(i) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 319F-1.

“(ii) APPLICATION OF PROVISIONS.—Provisions in such section 319F-1 that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

“(iii) AUTHORITY TO LIMIT COMPETITION.—For purposes of applying section 319F-1(b)(1)(D) to this paragraph, the phrase ‘BioShield Program under the Project BioShield Act of 2004’ shall be deemed to mean the countermeasure and product advanced research and development program under this section.

“(iv) AVAILABILITY OF DATA.—The Secretary may require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, relevant data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

“(C) ADVANCE PAYMENTS; ADVERTISING.—The authority of the Secretary to enter into contracts under this section shall not be limited by section 3324(a) of title 31, United States Code, or by section 3709 of the Revised Statutes of the United States (41 U.S.C. 5).

“(D) MILESTONE-BASED PAYMENTS ALLOWED.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

“(E) FOREIGN NATIONALS ELIGIBLE.—The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people and are consistent with National security.

“(F) ESTABLISHMENT OF ADVANCED RESEARCH CENTERS.—The Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers in accordance with section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3)), provided that such centers are consistent and complementary with the duties described in paragraph (4), and are consistent and complementary with, and deemed necessary after considering the availability of, existing federally-supported basic research programs.

“(6) VULNERABLE POPULATIONS.—In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to the emergency health security needs of children and other vulnerable populations.

“(7) PERSONNEL AUTHORITIES.—

“(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—In addition to any other personnel authorities, the Secretary may—

“(i) without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

“(ii) compensate them in the same manner in which individuals appointed under section 9903

of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

“(B) SPECIAL CONSULTANTS.—In carrying out this section, the Secretary may—

“(i) appoint special consultants pursuant to section 207(f); and

“(ii) accept voluntary and uncompensated services.

“(C) INAPPLICABILITY OF CERTAIN PROVISIONS.—

“(1) DISCLOSURE.—

“(A) IN GENERAL.—The Secretary shall withhold from disclosure under section 552 of title 5, United States Code, specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development funded by the Secretary that reveal vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5, United States Code.

“(B) OVERSIGHT.—Information subject to non-disclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years to determine the relevance or necessity of continued nondisclosure.

“(2) FEDERAL ADVISORY COMMITTEE ACT.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to a working group of BARDA or to the National Biodefense Science Board under section 319M.

“(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out advanced research and development under this section, there are authorized to be appropriated \$160,000,000 for each of the fiscal years 2007 and 2008. Such authorizations are in addition to other authorizations of appropriations that are available for such purpose. Amounts appropriated under the preceding sentence are available until expended.

“(e) DEFINITIONS.—For purposes of this section:

“(1) BARDA.—The term ‘BARDA’ means the Biomedical Advanced Research and Development Authority.

“(2) OTHER TRANSACTIONS.—The term ‘other transactions’ means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10, United States Code.

“(3) QUALIFIED COUNTERMEASURE.—The term ‘qualified countermeasure’ has the meaning given such term in section 319F-1.

“(4) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term ‘qualified pandemic or epidemic product’ has the meaning given the term in section 319F-3.

“(5) ADVANCED RESEARCH AND DEVELOPMENT.—

“(A) IN GENERAL.—The term ‘advanced research and development’ means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

“(i) are conducted after basic research and preclinical development of the product; and

“(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

“(B) ACTIVITIES INCLUDED.—The term under subparagraph (A) includes—

“(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

“(ii) design and development of tests or models, including animal models, for such testing;

“(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

“(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

“(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

“(6) RESEARCH TOOL.—The term ‘research tool’ means a device, technology, biological material, reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

“(7) PROGRAM MANAGER.—The term ‘program manager’ means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

“(8) PERSON.—The term ‘person’ includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.

“SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND WORKING GROUPS.

“(a) IN GENERAL.—

“(1) ESTABLISHMENT AND FUNCTION.—The Secretary shall establish the National Biodefense Science Board (referred to in this section as the ‘Board’) to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

“(2) MEMBERSHIP.—The membership of the Board shall be comprised of individuals who represent the Nation’s preeminent scientific, public health, and medical experts, as follows—

“(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

“(B) four individuals representing the pharmaceutical, biotechnology, and device industries;

“(C) four individuals representing academia; and

“(D) five other members as determined appropriate by the Secretary.

“(3) TERM OF APPOINTMENT.—A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

“(4) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

“(5) DUTIES.—The Board shall—

“(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats to biodefense or public health security posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

“(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b); and

“(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities.

“(6) MEETINGS.—

“(A) INITIAL MEETING.—Not later than one year after the date of enactment of the Bio-defense and Pandemic Vaccine and Drug Development Act of 2006, the Secretary shall hold the first meeting of the Board.

“(B) SUBSEQUENT MEETINGS.—The Board shall meet at the call of the Secretary, but in no case less than twice annually.

“(7) VACANCIES.—Any vacancy in the Board shall not affect its powers, but shall be filled in the same manner as the original appointment.

“(8) CHAIRPERSON.—The Secretary shall appoint a chairperson from among the members of the Board.

“(9) POWERS.—

“(A) HEARINGS.—The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this subsection.

“(B) POSTAL SERVICES.—The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

“(10) PERSONNEL.—

“(A) EMPLOYEES OF THE FEDERAL GOVERNMENT.—A member of the Board that is an employee of the Federal Government may not receive additional pay, allowances, or benefits by reason of the member's service on the Board.

“(B) OTHER MEMBERS.—A member of the Board that is not an employee of the Federal Government may be compensated at a rate not to exceed the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the actual performance of duties as a member of the Board.

“(C) TRAVEL EXPENSES.—Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

“(D) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Board with the approval for the contributing agency without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

“(b) DEFINITIONS.—Any term that is defined in section 319L and that is used in this section shall have the same meaning in this section as such term is given in section 319L.

“(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated \$1,000,000 to carry out this section for each of the fiscal years 2007 and 2008.”

SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED BY PROJECT BIOSHIELD.

(a) QUALIFIED COUNTERMEASURES.—Section 319F-1(a)(2) of the Public Health Service Act (42 U.S.C. 247d-6a(a)(2)) is amended—

(1) by amending subparagraph (A) to read as follows:

“(A) diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, or from any chemical, radiological, or nuclear agent, that may cause a public health emergency affecting national security; or”;

(2) in subparagraph (B), by striking “treat, identify, or prevent harm” and inserting “diagnose, mitigate, prevent, or treat harm”; and

(3) by adding after and below subparagraph (B) the following:

“If through publication in the Federal Register the Secretary makes a determination that there is credible evidence that a biological agent has the potential to cause an epidemic or pandemic that may constitute a public health emergency, a countermeasure to such agent shall, without further administrative action, be considered a qualified countermeasure within the meaning of this paragraph.”.

(b) SECURITY COUNTERMEASURES.—Section 319F-2(c)(1)(B)(i)(I) of the Public Health Service

Act (42 U.S.C. 247d-6b(c)(1)(B)(i)(I)) is amended by striking “to treat” the first place such term appears and all that follows through “from a condition” and inserting the following: “to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin or from any chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition”.

SEC. 5. TECHNICAL ASSISTANCE.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

“SEC. 565. TECHNICAL ASSISTANCE.

“The Secretary, in consultation with the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of qualified countermeasures (as defined in section 319F-1 of the Public Health Service Act), security countermeasures (as defined in section 319F-2 of such Act), or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.”.

SEC. 6. PROCUREMENT.

Section 319F-2 of the Public Health Service Act (42 U.S.C. 247d-6b) is amended—

(1) in the section heading, by inserting “**AND SECURITY COUNTERMEASURE PROCUREMENTS**” before the period; and

(2) in subsection (c)—

(A) in the subsection heading, by striking “BIOMEDICAL”;

(B) in paragraph (5)(B)(i), by striking “to meet the needs of the stockpile” and inserting “to meet the stockpile needs”;

(C) in paragraph (7)(B)—

(i) by striking the subparagraph heading and all that follows through “Homeland Security Secretary” and inserting the following: “INTER-AGENCY AGREEMENT; COST.—The Homeland Security Secretary”; and

(ii) by striking clause (ii);

(D) in paragraph (7)(C)(ii)—

(i) by amending clause (I) to read as follows:

“(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract. Provided that the specified milestones are reached, these advance payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.”; and

(ii) by adding at the end the following:

“(VII) PROCUREMENT OF MULTIPLE PRODUCTS AND TECHNOLOGIES.—The Secretary may enter into multiple transactions for the procurement of multiple technologies and products from multiple manufacturers of security countermeasures in order to mitigate against the risks associated with dependence on a single supplier or technology.

“(VIII) SALES EXCLUSIVITY.—The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)).

“(IX) SURGE CAPACITY.—The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

“(X) ADDITIONAL CONTRACT TERMS.—The Secretary, in any contract for procurement under this section, may specify—

“(aa) the dosing and administration requirements for countermeasures to be developed and procured;

“(bb) the amount of funding that will be dedicated by the Secretary for development and acquisition of the countermeasure; and

“(cc) the specifications the countermeasure must meet to qualify for procurement under a contract under this section.”; and

(E) in paragraph (8)(A), by adding at the end the following: “In the case of such agreements by the Secretary, the Secretary may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary, and such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, United States Code, except that all such orders shall be processed under the terms established under this section for the procurement of countermeasures.”

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Georgia (Mr. DEAL) and the gentlewoman from California (Ms. ESHOO) each will control 20 minutes.

The Chair recognizes the gentleman from Georgia.

GENERAL LEAVE

Mr. DEAL of Georgia. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on this legislation and insert extraneous material on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Georgia?

There was no objection.

Mr. DEAL of Georgia. Mr. Speaker, I yield myself such time as I may consume.

I rise today in strong support of H.R. 5533, the Biodefense and Pandemic Vaccine and Drug Development Act of 2006.

Like the NIH Reform Act that we will be considering later this evening, this legislation is the end product of a cooperative, bipartisan effort to help improve research outputs for the benefit of all Americans should the unspeakable happen here again on American soil.

As my colleagues are no doubt aware, biodefense is an area where the Federal Government must take a strong role because there is no business model that will support the investments we need without a clear path from the Federal Government. However, we also know that the expertise in this area mostly lies with the private sector, so we must make sure that we facilitate a strong working partnership.

Project BioShield was signed into law on July 21, 2004, to help encourage the development of new bioterrorism countermeasures. The legislation provided procedures for bioterrorism-related procurement, hiring and awarding of research grants in an effort to make it easier for United States Department of Health and Human Services to quickly commit substantial funds to countermeasure projects.

This past April, the Subcommittee on Health held a hearing on Project BioShield; and at this hearing our expert witnesses identified a number of barriers to fully realizing Project BioShield's potential. They highlighted the fact that there is no single point of authority within the Department of Health and Human Services for the advanced research and development of medical countermeasures to make important procurement decisions. Additionally, HHS has limited purchasing and contractual flexibility, and this inefficient structure and limited flexibility exacerbates the shortcomings of the status quo.

Drug and vaccine development is unnecessarily lengthy, often taking between 8 and 12 years, and many potential products fail prematurely following basic research due to limited funding for advanced research and development. There simply is not enough motivation for academic researchers, drug and vaccine manufacturers and other possible partners to commit substantial resources to bring new and improved products to the market quickly.

I believe that the legislation before us today helps address the problems raised in our hearing and represents a huge improvement over the status quo.

I would like to commend the chairman of our Energy and Commerce Committee, Chairman BARTON of Texas; Congressman MIKE ROGERS of Michigan; and Congresswoman ANNA ESHOO of California for their strong leadership on this legislation that builds on the achievements of the Project BioShield Act and takes fur-

ther steps to identify and promote medical countermeasures to bioterrorism and other public health emergencies, including potential pandemic infectious diseases.

I urge my colleagues to support this legislation.

Mr. Speaker, I reserve the balance of my time.

Ms. ESHOO. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I am really proud to be the Democratic sponsor of this bill; and I want to salute my friend and my colleague, Representative ROGERS, for the work that he has done. We have really enjoyed working together, and I think that the best part of this all is that our work has really produced something that is important for the American people. So I want to thank him for everything that he has done to see that the bill is on the floor today.

This legislation really addresses a very urgent issue which is critical to our Nation's security and our public health.

A month after the 9/11 attacks on New York and Washington, our country was attacked again. When we were attacked that second time, it was when envelopes of anthrax spores were mailed to several media outlets and congressional offices. The attacks killed five people, they crippled our mail service here on the Hill and cost hundreds of millions of dollars to clean up.

We are now observing the spread of a virulent new strain of Avian influenza, the so-called Asian bird flu, in Asia and around the world, causing nearly 150 deaths and threatening to become the next deadly pandemic.

Whether the threat is man-made bioterrorism or a highly infectious disease, our country is at risk, and we are losing precious time in the race to develop effective countermeasures that could save thousands or even millions of lives.

In hearings earlier this year on the Project BioShield Act, it was apparent that gaps remained in our effort to address these threats to the public health.

In particular, we learned that very few companies are willing to risk their limited resources to develop the vaccines and the antidotes to respond to chemical, biological, radiological or nuclear attacks or to a fast-spreading influenza.

Given the risks and the costs involved, it is not surprising that companies would rather pursue the next blockbuster cancer medicine or cholesterol medicine rather than take a chance on an uncertain market where the government is likely to be the only customer.

So having heard this in the hearings, we rolled our sleeves up. We understood that Project BioShield does not address the problem. While the law set aside \$5.6 billion over 10 years to obtain drugs for the Strategic National Stockpile, companies receive very little com-

pensation until they can deliver a minimum number of doses. As a result, many of these potential drugs languish in the laboratory in what is known as the "Valley of Death."

As with any drug, the development of biodefense drugs require efficacy trials, toxicity testing, production design and a range of other activities that are expensive but necessary to determine whether a drug will work, whether it is safe and how it will be manufactured.

The centerpiece of this legislation that we are on the floor on behalf of this evening develops a new, or places a new office within HHS, the Biomedical Advanced Research and Development Authority, BARDA, which would be a single point of Federal authority for the development of medical countermeasures.

This bill will empower BARDA to make milestone payments to drug developers at key stages of their work, helping to reduce financial risks of taking on this great challenge. In other words, we are going to get the job done.

I urge my colleagues to support this important legislation, which will ensure that our country does its best to prepare for the worst.

Mr. Speaker, I reserve the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I am pleased to yield 5 minutes to the gentleman from Michigan (Mr. ROGERS), the author of the legislation.

Mr. ROGERS of Michigan. Mr. Speaker, I rise today in strong support of H.R. 5533, the Biodefense and Pandemic Vaccine and Drug Development Act of 2006.

I would like to thank Chairman BARTON and Chairman DEAL and the Energy Committee staff for their continued support on this effort.

I want to thank my colleague and friend, Congresswoman ANNA ESHOO, and her staff for your commitment, your energy, your counsel and your enthusiasm to get this bill as far as we have come. Thank you very much. It has been a joy to work with you.

And I have to say at the time of this intense pre-election partisanship, I am thankful that we might serve as an example to many, that you can reach across the aisle to pass important legislation that affects the American people so deeply as their future security, the security of their children and their families and the well-being of the United States of America. Thank you for working with us. I appreciated the opportunity to do that.

I would also like to recognize the administration and their willingness to work with us to build upon Project BioShield, of which they really led the charge. We found that it was not sufficient, it needed some improvement, but it was very forward leaning of this President to come out and establish for the first time BioShield, knowing that the threat was real from terrorists around the country and trying to develop at least a program that would deal with the bioterror threat to the

United States. They have been so willing to work with us in finding out what worked and what did not work and this second round we think improves BioShield dramatically and really has to happen if we are going to have protection against biotreatments in the future.

The efforts include both offensive and defensive ways to find new developments and better treatments for those infected by bioterrorist attacks and naturally occurring attacks, as was mentioned by the mention of the bird flu.

The problems that we have discovered in looking at BioShield was that there was no single point of authority within HHS for the advanced research and development of countermeasures and quick procurement decisions, and, really, there is only one customer for these type of vaccines, and this is the place where we found some difficulty. There is really only one customer, and that customer is the people of the United States, the government of the United States. With a single source contract it is very hard to attract venture capital, very hard to get private industry excited about developing something if they did not know where the Federal Government was going to be when it came to purchasing something that we are the only ones that were going to buy it, a hard place to be.

So we came up with the single point of authority to make quick decisions; and the Valley of Death takes a long time, 8 to 12 years, to develop these vaccines, very labor intensive, a lot of intellectual power applied to coming up with the right vaccine to be the right prophylactic for what we know is a bioterrorism or natural-occurring event. That Valley of Death, because we are the single source of those contracts, was very real and stalling what we know is great research to happen for the cure and the development of these vaccines.

Also, we found that it did not motivate academic researchers, drug and vaccine manufacturers and other possible partners to commit substantial resources.

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What this bill does, Mr. Speaker, is address all those issues and gives us a framework to go forward and bring out the best in our scientific community, our academic community, our producing community to come up with the right safety net for the protection of the United States when it comes to bioterror threats and natural occurring threats in and around our societies, which we know is already here, bird flu mentioned, but we also know the real threat of bioterrorism as well.

I would hope, Mr. Speaker, that we could encourage the Senate to take our lead here and set aside any partisanship that may arise in the course of this bill in the Senate and take quick action. This really means the safety and security of every family in this

country. Bioterrorism is, unfortunately, a reality in 2006 and beyond; and they need to set aside any differences they may have in the Senate and take this bill up. So I would encourage Senate Democrat leadership to do just that.

I would also commend Senator BYRD, who has created this bipartisan product, and urge they move this product as soon as possible. And I would also urge, Mr. Speaker, that this important piece of legislation be passed as quickly as possible.

Ms. ESHOO. Mr. Speaker, I just want to close. I do not think I have any other individuals to come to the floor to speak on this this evening.

I also want to thank our staffs, because they have worked exceedingly hard and exceedingly well with one another, both from Mr. ROGERS' staff, certainly mine, with Steve Keenan and Jennifer Nieto, and everyone that helped them in my office, as well as John Ford on the minority staff of the committee, as well as the majority staff. I salute all of you. I thank you. I am proud of the work we have been able to do.

Mr. DINGELL. Mr. Speaker, I rise in support of H.R. 5533, the "Biodefense and Pandemic Vaccine and Drug Development Act of 2006".

In an effort to respond to the new era of heightened threats to our national security and the increased risk of harm to Americans, Congress passed the "Project Bioshield Act" in July of 2004. The basic purpose of Project Bioshield was to support research that would lead to the development and availability of "countermeasures" to combat public health emergencies that threaten our national security. The main provisions of this law included: (1) flexible procedures for bioterrorism-related procurement, hiring of personnel, and awarding of research grants; (2) guaranteeing a Federal Government market for new biomedical countermeasures; and (3) permitting emergency use of unapproved countermeasures.

Building on the Project Bioshield Act, H.R. 5533 takes further steps to identify potential medical countermeasures to protect the public health and national security from biological, chemical, radiological, and nuclear threats. Additionally, this legislation ensures the rapid development of medical countermeasures against such threats, including potential pandemic infectious diseases and it seeks to expand the collaboration and coordination between government and the private sector so that we can effectively respond in the event of a public health emergency.

Since the implementation of Project Bioshield, it has become apparent that certain barriers still exist to the development of countermeasures. Many promising countermeasures are not making it through the advanced research and development stages necessary to bring products to the point of eligibility for procurement. H.R. 5533 seeks to rectify this impediment to advanced-stage countermeasure development.

This legislation seeks to streamline the countermeasure research and development process and create a single point of Federal authority by creating a new office called the Biomedical Advanced Research and Develop-

ment Agency (BARDA) within the Department of Health and Human Services. BARDA would establish a "one stop shop" agency for advanced research and development of medical countermeasures, including drugs and vaccines to respond to bioterrorism and natural disease outbreaks. This agency would be responsible for directing and coordinating collaboration among HHS entities, other Federal agencies, relevant industries, academia, and other individuals with respect to countermeasure research and development.

I commend my colleagues, Representatives ESHOO and ROGERS, for their diligent and impassioned work on this issue. This is a good bill and I urge my colleagues to support it.

Mr. BARTON of Texas. Mr. Speaker, please include this exchange of correspondence in the RECORD for H.R. 5533.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, September 26, 2006.

Hon. TOM DAVIS,
Chairman, Committee on Government Reform,
House of Representatives, Washington, DC.

DEAR CHAIRMAN DAVIS: I acknowledge and appreciate your willingness not to exercise your referral of H.R. 5533, Biodefense and Pandemic Vaccine and Drug Development Act of 2006. In doing so, I agree that your decision to forgo further action on the bill will not prejudice the Committee on Government Reform with respect to its jurisdictional prerogatives on this legislation or similar legislation.

Further, I recognize your right to request conferees on those provisions within the Committee on Government Reform's jurisdiction should they be the subject of a House-Senate conference on this or similar legislation.

I will include your letter and this response in the Congressional Record during floor consideration of H.R. 5533.

Sincerely

JOE BARTON,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC, September 26, 2006.

Hon. JOE BARTON,
Chairman, House Committee on Energy and Commerce,
Rayburn House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: On September 20, 2006, the House Committee on Energy and Commerce reported H.R. 5533, the Biodefense and Pandemic Vaccine and Drug Development Act of 2006. As you know, the bill includes provisions within the jurisdiction of the Committee on Government Reform, specifically section 3 of the bill that would exempt the Authority proposed to be created by this legislation from portions of the Federal Advisory Committee Act and the Freedom of Information Act. Section 3 would also authorize the Secretary of Health and Human Services to utilize "other transaction" procurement authority.

In the interests of moving this important legislation forward, I agreed to waive sequential consideration of this bill by the Committee on Government Reform. However, I did so only with the understanding that this procedural route would not be construed to prejudice the Committee on Government Reform's jurisdictional interest and prerogatives on this bill or any other similar legislation and will not be considered as precedent for consideration of matters of jurisdictional interest to my Committee in the future.

I respectfully request your support for the appointment of outside conferees from the

Committee on Government Reform should this bill or a similar bill be considered in a conference with the Senate. Finally, I request that you include this letter and your response in the Congressional Record during consideration of the legislation on the House floor.

Thank you for your attention to these matters.

Sincerely,

TOM DAVIS.

Mr. WAXMAN. Mr. Speaker, the bill before us would create a new agency within the Department of Health and Human Services, the Biomedical Advanced Research and Development Authority, or BARDA. I support creating this new agency. However, some provisions in the bill raise concerns because they waive a number of existing Federal statutes enacted to ensure proper government oversight. I want to express my reservations over these provisions, and urge that they be addressed in conference.

This bill contains exemptions from important federal open government laws designed to ensure accountability and transparency, like the Freedom of Information Act (FOIA) and federal procurement law. These open government laws are within the jurisdiction of the Committee on Government Reform, on which I am the ranking member, but unfortunately, the Government Reform Committee did not have an opportunity to consider the bill.

FOIA is the central law that guarantees public access to government information. It establishes the presumption that people should be able to access information held by the government. FOIA contains exemptions that prevent the disclosure of information in the case where harm could result from disclosure—including exemptions for classified information, trade secrets, information compiled for law enforcement purposes, and internal agency documents that would be exempt from discovery in litigation.

H.R. 5533 establishes a new FOIA exemption, requiring the Secretary to withhold from public disclosure "specific technical data of scientific information that is created or obtained during countermeasure research and product advanced development funded by the Secretary that reveal vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats." While this exemption appears narrow in scope, the Administration has a long record of interpreting narrow language broadly to withhold public information. Unless there is a compelling reason why the existing FOIA exemptions are inadequate—which there does not appear to be in this case—it is unwise to add new exemptions to FOIA. Moreover, the language of the new exemption is not clear. The language applies to any "advanced research and development that is funded by the Secretary," which may inappropriately extend the exemption far beyond BARDA to other research funded by the Department of Health and Human Services.

Another issue is so-called "other transaction authority." This authority is essentially a waiver from most federal procurement law—everything from competition requirements, to auditing and pricing safeguards, to the Buy America and Drug-free workplace laws. The authority was originally developed to help DOD in attracting smaller contractors to federal research and development contracts, though in practice it has not often been used to accomplish that

objective. While I am not necessarily opposed to granting BARDA other transaction authority, I have yet to hear a convincing rationale for its necessity. If such a rationale exists, we should explore ways to limit its application at BARDA to those instances where it is truly needed, as opposed to the blanket grant of authority currently in H.R. 5533.

Finally, H.R. 5533 exempts all advisory committees established under the bill from section 14 of the Federal Advisory Committee Act. Section 14 was added to the FACA law because Congress decided that there was a proliferation of advisory committees and that it is important to ensure that they should continuously be reviewed to ensure their ongoing necessity. Again, there is no clear explanation for why this waiver of current law is necessary, or what interests would be protected by exempting the committees from renewal requirements.

All of these issues are within the jurisdiction of the Government Reform Committee, and I hope they can be addressed as this bill moves forward in the legislative process.

Ms. ESHOO. Mr. Speaker, I yield back the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I have no other requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Georgia (Mr. DEAL) that the House suspend the rules and pass the bill, H.R. 5533, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

ARROWROCK PROJECT HYDRO-ELECTRIC LICENSE EXTENSION BILL

Mr. OTTER. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4377) to extend the time required for construction of a hydroelectric project, and for other purposes.

The Clerk read as follows:

H.R. 4377

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ARROWROCK HYDROELECTRIC PROJECT.

Notwithstanding the time period specified in section 13 of the Federal Power Act (16 U.S.C. 806) that would otherwise apply to the Federal Energy Regulatory Commission project numbered 4656, on request of the licensee, the Commission shall—

(1) if the license for the project is in effect on the date of the enactment of this Act, extend the period for commencing construction of project works for a period of 3 years beginning on the date of enactment of this Act; or

(2) if the license for the project has been terminated before the date of enactment of this Act, reinstate the license and extend the period for commencing construction of project works for an additional 3-year period beginning on the date of enactment of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Idaho (Mr. OTTER) and the gentleman

from Virginia (Mr. BOUCHER) each will control 20 minutes.

The Chair recognizes the gentleman from Idaho.

GENERAL LEAVE

Mr. OTTER. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on this legislation and to insert extraneous material.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Idaho?

There was no objection.

Mr. OTTER. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 4377, the Arrowrock Project Hydroelectric License Extension Bill, which extends the time in the hydroelectric license to begin construction of a 15-megawatt project by 3 years from the date of passage of this bill. The facility will be built at the existing Arrowrock Dam on the Boise River in Idaho and has been designated to minimize impacts there.

Over the past decade, this project has been delayed by a number of factors not necessarily within the control of the project developer, including delays related to the bull trout being declared threatened under the Endangered Species Act. We have now solved that problem and we have been assured that the project is ready to go once the license is extended.

This project has bipartisan support. It will further develop the hydroelectric facilities at existing dams, something we promoted in the Energy Policy Act of 2005, so I urge my colleagues to support the bill.

Mr. Speaker, I reserve the balance of my time.

Mr. BOUCHER. Madam Speaker, I yield myself such time as I may consume.

I rise today in support of H.R. 4377, a bill which would require the Federal Energy Regulatory Commission to extend for a 3-year period the deadline for commencing construction on the proposed Arrowrock Hydroelectric Project in the State of Idaho.

The project was originally licensed in 1989, but due to extenuating circumstances, construction has not begun on the project as of this time. One reason for the delay was the need for required consultations with regard to the bull trout, a species which was listed as threatened only after the original license had been issued. The project is now moving forward with those required consultations.

The bill before us would simply extend the license to give the licensee more time in order to finalize the project and get construction under way. This measure was approved by the Energy and Commerce Committee by voice vote, along with four other hydroelectric licensing bills which we are also considering this evening.

I urge my colleagues to approve this measure.